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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ezio Bombardelli

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EXAMINER

MCCORMICK, MELENIE LEE

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,980	Applicant(s) BOMBARDELLI, EZIO	
	Examiner MELENIE MCCORMICK	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 2,5,7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of the species esculoside, extracts containing forskolin, ximenynic acid and the optional compound *Ginkgo biloba* dimeric flavones in the reply filed on 7 March is acknowledged. Upon further consideration, the species visnadin and forskolin have been rejoined and examined. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that while Applicant submits claims 1-9 are drawn to the elected species, that claims 1, 3-4, 6, and 8-9 are drawn to the elected species.

Claims 2, 5, and 7-8 are withdrawn from consideration.

Claims 1, 3-4, 6, and 9 are presented for examination on the merits.

Claim Objections

Claims 1, 3-4 and 6 are objected to because of the following informalities: Claim 1 recites "compositions". Applicants are entitled to one invention per patent. All other claims depend from claim 1 and recite "compositions" and are objected to for this same reason. Appropriate correction is required.

Claim 6 is also objected to because the word 'and' or the word 'or' should follow 'forskolii purified extract'.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'or extracts containing it' in line 2 and 'thereof which contain it' in line 6 . This lacks clear antecedent basis because 'it' is ambiguous. It is suggested that 'it' be replaced with 'forskolin' to more clearly define the claimed subject matter.

Claim 9 also recites 'or extracts containing it' in line 3 and 'thereof containing it' in line 7 and is rejected for the same reason as claim 1, as discussed above.

Claim 4 recites the limitation "the ethyl ester" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested that this term be replaced by 'the ethyl ester of ximenynic acid'.

Claim 6 is vague and indefinite because it is not clear if Applicants intend to claim esculodise, *Coleus forskolii* purified extract *and* ximenynic acid ethyl ester or if Applicants intend to claim esculodise, *Coleus forskolii* purified extract *or* ximenynic acid ethyl ester.

Claim 9 provides for the use of a combination of esculoside or visnadine, forskolin or extracts containing it, or alternatively, or purified lipophilic extracts of plants of the genus *ipomea*; esters of ximenynic acid; optionally, at least one compound selected from icarin or derivatives or extracts thereof which contain it, amentoflavone, and *Ginkgo biloba* dimeric flavones for the preparation of compositions for the topical treatment of sexual dysfunctions, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al. (EP 0693278) and Nishizawa et al. (JP 09157136).

Because it is not clear if a method is being claimed in claim 9, claim 9 considered a composition for prior art purposes (see rejection under 35 U.S.C. 112, second paragraph above).

Bombardelli et al. beneficially teach that esculoside and esters of ximenyic acid are useful in the treatment of hair loss and in the stimulation of hair re-growth (see e.g. page 2, lines 33-35). Bombardelli et al. further teach that visnadin is also effective for this purpose (see e.g. page 2, lines 3-8) and that esculoside can replace visnadin (see e.g. page 2, lines 29-32). Bombardelli et al. also teaches that the ester of ximenyic acid is the ethyl ester (see e.g. page 2, line 7).

Bombardelli et al. do not explicitly teach that that forskolin or an extract containing forskolin is also used in treating hair loss or stimulating hair re-growth.

Nishizawa et al. beneficially teach that forskolin or an extract of a root of *Coleus forskolin* are used in a hair breeding agent (see e.g. English translation [0002]). Nishizawa et al. further teaches that the hair breeding agent has hair growth promoting activity (see e.g. [0001]).

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the esculoside and ethyl ester of ximenyic acid

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taught by Bombardelli et al. with the forskolin or extract of a root of *Coleus forskolin* taught by Nishizawa et al. in order to prepare a composition comprising esculoside, ethyl ester of ximenyic acid and forskolin or extract of a root of *Coleus forskolin*, as instantly claimed because each were used in the prior art to promote hair re-growth.

“The idea for combining them flows logically from their having been used individually in the prior art”; *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, See *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). It would have also have been obvious to use visnadin instead of esculoside because Bombardelli et al. teaches that they can be exchanged for each other.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 3-4, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Pierro (WO 02/098436 A) and Dweek (1999) in view of Bombardelli (US 5,376,371).

Di Pierro beneficially teaches a pharmaceutical and/or cosmetic composition containing escin, Ginkgo biloba dimeric flavones, ethyl ximentiate, and standardized Coleus forskolii extract (see e.g. page 2). Di Pierro further teaches that escin is derived from horse-chestnut seeds and has anti-edematous properties, probably due to a modification of the capillary permeability (see e.g. page 3, lines 3-5). Di Pierro also teaches that ethyl ximentiate is the ethyl ester of ximenininc acid (see e.g. page 4, lines 305) and that the standardized Coleus forskolii extracts contains forskolin therein (see e.g. page 4, lines 8-10). Di Pierro teaches that this composition is intended to be used to treat localized adiposities and cellulite (see .g. page 1, lines 1-2).

Di Pierro does not explicitly teach that the composition contains esculoside. Di Pierro also does not explicitly teach that the dimeric flavones of *Ginkgo biloba* comprise amentoflavone.

Dweek beneficially teaches that esculoside is derived from horse chestnut tree and that increases capillary resistance and reduces oedema (see e.g. page 2).

Bombardelli beneficially teaches that amentoflavone is useful in compositions for reducing fat deposits (see e.g. col 4, example 4 and claim 3).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the esculoside taught by Dweek for the escin taught by Di Perro in the composition comprising *Ginkgo biloba* dimeric flavones, ethyl ximentiate and extract containing forskolin. A person of ordinary skill in the art would have had a reasonable expectation of success in doing so based upon the teaching of Dweek that esculoside increases capillary resistance and reduces oedema, which is the same function taught by Di Pierro of escin. A person of ordinary skill in the art would have also had a reasonable expectation of success in using amentoflavone as the particular dimeric flavone from *Ginkgo biloba* based upon the disclosure Bombardelli that amentoflavone is useful in fat deposit reduction (see e.g. col 4, Example 4 and claim 3). This is especially true given that is essentially the same the intended use that Di Pierro teaches for the composition, which is treating localized adiposities and cellulite.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the

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intended use does not create a structural difference, thus the intended use is not limiting.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655